

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0928]

DMB

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Agency Information Collection Activities; Submission for OMB Review; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Samples and Protocols (OMB Control Number 0910-0206)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity,

and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products as follows: Sections 640.101(f) (21 CFR 640.101(f)) (Immune Globulin (Human)), 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 640.101(f)(2) requires for each lot of Immune Globulin (Human) product, the submission of all protocols relating to the history of the product and all results of all tests prescribed in the additional standards for the product.

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires a protocol containing information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a

copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of any licensed biological product. Respondents to the collection of information under §§ 640.101(f)(2), 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously. The estimated number of respondents for each regulation is based on the annual number of manufacturers that

submitted samples and protocols for biological products, including submissions for lot release, surveillance, licensing, or export. There are an estimated 350 manufacturers of licensed biological products, however, based on information obtained from FDA's data base system, approximately 100 manufacturers submitted samples and protocols in 1998, under the regulations cited previously. FDA estimates that approximately 86 manufacturers submitted protocols under § 610.2, and 14 manufacturers submitted protocols under the regulations for the specific products. FDA had previously estimated 80, instead of 90, manufacturers would submit samples and protocols annually under all the regulations cited previously to account for biotechnology firms that are exempt from lot release requirements. Because biotechnology firms may still be required to submit samples and protocols for purposes other than lot release, as explained previously, the number of respondents for § 610.2 in this estimate includes them. The slight increase in the total estimated number of respondents (100) is due to a normal variation in annual submissions.

The total annual responses are based on FDA's final actions completed in fiscal year 1998, which totaled 7,221, for the various submission requirements of samples and protocols for biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of March 22, 2000 (65 FR 15341), the agency requested comments on the proposed collection of information. No significant comments were received.

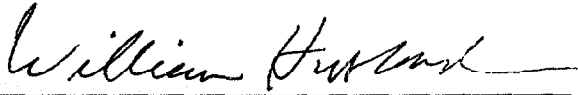
FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	86	82.72	7,114	3	21,342
640.101(f)(2)	5	4.40	22	5	110
660.6(b)	6	11.33	68	5	340
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	8	16	5	80
Total	100		7,221		21,878

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 27, 2000



William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

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